Vaccine Safety: The Providers Role
Providers Play an Important Role in Vaccine Safety

The United States currently has the safest, most effective vaccines in its history. Federal regulations require that vaccines undergo years of testing before they can be licensed. Once in use, vaccines are monitored continually for safety and efficacy. As an immunization provider, you also play a key role in helping to ensure the safety and efficacy of vaccines through proper:

- Vaccine storage and handling
- Vaccine administration
- Timing and spacing of vaccine doses
- Observation of precautions and contraindications
- Management of vaccine side effects
- Reporting of suspected side effects
- Communication about vaccine benefits and risks

Vaccine Storage and Administration
To achieve the best possible results from vaccines, carefully follow the recommendations for storage, handling, and administration found in each vaccine's package insert. Here are other steps you can take to help ensure vaccine safety:

- Inspect vaccines upon delivery and monitor refrigerator and freezer temperatures to assure maintenance of the cold chain.
- Rotate vaccine stock so the oldest vaccines are used first.
- Never administer a vaccine later than the expiration date.
- Administer vaccines within the prescribed time periods following reconstitution.
- Wait to draw vaccines into syringes until immediately prior to administration.
- Never mix vaccines in the same syringe unless they are specifically approved for mixing by the Food and Drug Administration (FDA).
- Record vaccine and administration information, including lot numbers and injection sites, in the patient's record.
- If errors in vaccine storage and administration occur, take corrective action immediately to prevent them from happening again and notify public health authorities.

Timing and Spacing
The timing and spacing of vaccine doses are two of the most important issues in the appropriate use of vaccines. To ensure optimal results from each immunization, follow the currently recommended immunization schedules for children, adolescents and adults. The recommended childhood immunization schedule and influenza immunization recommendations are updated each year.

http://www.cdc.gov/nip/recs/child-schedule.pdf *

http://www.cdc.gov/mmwr/PDF/rr/rr5004.pdf *

The following points also should be remembered:

- Administering all needed vaccines during the same visit is important because it increases the likelihood that children will be fully immunized as recommended. Studies have shown that vaccines are as effective when administered simultaneously as they are individually and carry no greater risk for adverse side effects.
- There is no medical basis for giving combination vaccines separately. Administration of separated combination vaccines results in more discomfort.
- Some vaccines, like pediatric diphtheria and tetanus, produce increased rates of side effects when given too frequently. Good record keeping, maintaining careful patient histories, and adherence to recommended schedules can decrease the chances that patients receive extra doses of vaccines.

Observe Valid Contraindications

Contraindications and precautions to vaccination indicate when vaccines should not be given. A contraindication is a condition in a patient that increases the chance of a serious, adverse reaction. In general, a vaccine should not be administered when a contraindication is present. A precaution is a condition in a patient that *may* increase the chance of a serious side effect or render a vaccine ineffective. Normally, vaccination is deferred when a precaution is present. However, situations may arise when the benefits of vaccination outweigh the risk of a side effect, and the provider may decide to vaccinate the patient. Most contraindications and precautions are temporary and the vaccine may be given at a later time. The Centers for Disease Control and Prevention's (CDC) *Guide to Contraindications to Childhood Vaccinations* can be ordered on-line.

One key to preventing serious adverse reactions to vaccines is screening for contraindications and precautions. Every provider who administers vaccines should screen every patient before giving a vaccine dose. Sample screening questionnaires are available from the Immunization Action Coalition at www.immunize.org

Many conditions are often inappropriately regarded as contraindications to vaccination. In most cases, **the following are <u>not</u> contraindications:**

- Mild acute illness (e.g., diarrhea and minor upper-respiratory tract illnesses, including otitis media) with or without low grade fever
- Mild to moderate local reactions and/or low grade or moderate fever following a prior dose of the vaccine
- Current antimicrobial therapy
- Convalescent phase of illness
- Recent exposure to an infectious disease
- Premature birth
- Breastfeeding

Communicate About Vaccine Benefits and Risks

While you can do a number of things to help make vaccines as safe and effective as

possible, providing patients or parents/guardians with information about vaccines and immunization is equally important.

Before you administer **each dose** of certain vaccines, you are required by law to provide a copy of the most current Vaccine Information Statement (VIS) to either the adult vaccinee or to the child's parent/legal guardian. VIS are developed by the CDC and discuss the benefits and risks associated with specific vaccines. You must also record in the patient's chart the date that the VIS was given and the publication date of the VIS. Current VISs are available on the publications page.

Translations in over 20 languages are available at www.immunize.org

Other materials such as brochures, videos, and resource kits can assist you in communicating with patients or parents about vaccine benefits and risks. Parents can also be referred to credible Internet and hotline resources, such as:

CDC's National Immunization Information Hotline 1-800-232-2522 (English), 1-800-232-0233 (Spanish)

CDC's National Immunization Program web site at www.cdc.gov/nip

Be Prepared to Manage Vaccine Side Effects
Most people experience no side effects, or only mild ones, following immunization. Mild side effects may include soreness, swelling, or redness at the injection site or mild fever. Severe side effects, such as severe allergic reactions, following vaccination are extremely rare. However, any provider who administers vaccines should have procedures in place for the emergency care of a person who experiences an anaphylactic reaction. Epinephrine and equipment for maintaining an airway should be available for immediate use. All vaccine providers should be familiar with the office emergency plan, and should be certified in cardiopulmonary resuscitation.

Report Suspected Side Effects to VAERS
The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety monitoring program. VAERS collects information about adverse events (possible side effects) that occur after administration of U.S. licensed vaccines.

The National Childhood Vaccine Injury Act requires healthcare providers to report selected events occurring after vaccination to VAERS. However, VAERS encourages reporting of *any* clinically significant adverse event that occurs after administration of *any* vaccine licensed in the United States, *even if it is not certain* that the vaccine caused the event.

By reporting possible vaccine side effects to VAERS, you provide valuable information that is needed for the ongoing evaluation of vaccine safety. The CDC and FDA use VAERS information to ensure the safest strategies of vaccine use and to further reduce the rare risks associated with vaccines.

More information about VAERS, including reporting forms, can be obtained by calling the VAERS information line at 800-822-7967, or by visiting www.vaers.org.

For more information about the topics covered here see the *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)* at http://www.cdc.gov/nip/publications/ACIP-list.htm *

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* Accessibility note: The above ACIP and MMWR links are directly linked to .pdf formats but are also available in text-reader format at the following site: http://www.cdc.gov/mmwr/mmwrpvol.html. Also, text-reader versions of the VISs are available on the Vaccine Information Statements page.